

## **Guidance on Genetic Research**

Federal guidelines strongly advise IRBs to consider specific issues when reviewing clinical genetic research and to alert investigators engaged in such research to address these issues in their application for IRB approval. For IRB review purposes, genetic research is frequently divided into four categories: (1) pedigree studies; (2) positional cloning studies, including databanks; (3) DNA diagnostic studies and test development; and (4) gene transfer.

Unlike the risks presented by biomedical research, the primary risks of the first three categories of genetic research are risks of social and psychological harm rather than risks of physical injury. Genetic studies that generate information about subjects' personal health risks can provoke anxiety and confusion, damage familial relationships, and compromise subjects' insurability and employment opportunities. Although these genetic studies may be limited to a collection of family histories or blood draws, the IRB does not necessarily consider them to be minimal risk.

There are issues of particular concern to the IRB when research involves genetic testing. The protocol for such studies should provide the following information:

### **Genetic Analysis on Specimens Obtained from Research Subjects**

- the specific purpose of the genetic analysis;
- the particular genetic information that will be acquired;
- the kinds of biological specimens on which the genetic analysis will be performed;
- whether the genetic information will be linkable in any way to the subject;
- any potential consequences of the genetic information to insurability, employability or social esteem of the subject;
- how, if at all, the genetic information will be transmitted to the subject and whether the subject will be given the option to know/not know the results of the genetic analysis; and
- the provisions, if any, for genetic counseling.

### **Disclosure of Research Results & Confidentiality**

- State that this study is for research purposes only and no individual results will be given back to study participants. This will include information from final results of the study, interim results of the study and incidental findings.
- State that research results will never go into the medical record.
- State that confidentiality will be preserved to the fullest extent by the research team

### **Tissue Samples**

- State that if identifiers are to be maintained, they will be kept in a separate, secure locked location. Describe the security system on the computer, if the data is to be entered into a database.
- Explain that samples will be coded in order to remain confidential.

### **Provisions for future contact (re-contact);**

#### **Primary Use of Sample**

- State (if applicable) that the samples collected for this study may yield information that could be clinically relevant.
- Provide an option to be re-contacted if research information becomes applicable to clinical diagnosis/treatment. State that such contact could, if desired, lead to referral involving outside parties (e.g., a genetics clinic).
- State that additional consent will be necessary to transfer research data to the clinical setting. This consent must be submitted for review and approval.

- State that the investigators are not obligated to keep addresses/contact information in order to re-contact the subject.

**Special issues:**

**Secondary Uses and Third Party Uses**

- A **secondary use** is using a collected sample for any reasons other than the intended and documented purpose.
- A **third party** is any person outside the immediate research team.
- All secondary and third party uses of biological samples are restricted to **anonymized** or **anonymous** samples. This means the sample **cannot** be identified or linked to an individual by the 'secondary-use-researcher' or the 'third party'. Limited, non-identifying, demographic information may be retained on the sample.

Non-anonymous secondary research must follow the Genetic Research Gui

**Genetic Material to be Transferred to Research Subjects**

Principal Investigators must submit to the IRB a copy of proposals being prepared for submission to the FDA or the NIH Office for Recombinant DNA Activities (ORDA). The protocol should follow the outline for preparing an IND for submission to the FDA (See 21 CFR 312.23), and should address:

- the purpose of transfer of genetic material;
- any preclinical studies in suitable cell and animal models that were done to show efficacy and safety of the gene transfer protocol to be employed in the proposed project, and the outcomes;
- if the transfer of genetic material to the subject's cells will occur in vitro, the methods used to obtain tissues or cells from the subject, and the safety precautions to be taken in processing the cells;
- the characteristics of the genetic material to be transferred;
- whether a virus vector or helper virus is used in the transfer;
- how the genetic material will be administered to the research subjects;
- the measures that will be taken to preclude insertion of the genetic material into germ cells;
- the measures that will be taken to secure long-term follow-up of the subject, and whether there will be an autopsy in case of death; and
- if subjects with reproductive potential are involved, a description of the contraceptive measures to be taken for men and women during the active phase of the study.